

Food and Drug Administration Denver District Office Bldg. 20-Denver Federal Center P.O. Box 25087 6<sup>th</sup> Avenue & Kipling Street Denver, Colorado 80225-0087 Telephone: 303-236-3000 FAX: 303-236-3100

April 26, 2002

## WARNING LETTER

## CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. D. Gary Young Managing Director/Owner Aromatic Research & Technology, LLC d/b/a Young Living Essential Oils 250 S. Main Street Payson, Utah 84651

Reference #: DEN-02-12

Dear Mr. Young:

During an inspection of your facility on the dates of January 30 and February 26, 2002, a Food and Drug Administration (FDA) investigator documented violations of the Federal Food, Drug, and Cosmetic Act (the Act). Your Stevia Extract and Stevia Select products labeled as Dietary Supplements are actively promoted as conventional foods through labeling, including promotional literature and your web site, <a href="www.youngliving.com">www.youngliving.com</a>. When used as an ingredient of a conventional food, or when offered and intended for such use, stevia is considered a food additive. Therefore, stevia is an unapproved food additive that is unsafe within the meaning of Section 409 of the Act. The presence of stevia in your products renders them adulterated within the meaning of Section 402(a)(2)(C) of the Act.

Labeling your stevia products as Dietary Supplements does not necessarily make the products dietary supplements as provided for under the Act. Under the Dietary Supplement Health and Education Act of 1994, the definition of a dietary supplement does not include products represented for use as conventional foods [Section 201 (ff)(2)(B) of the Act].

Examples of claims that promote your stevia products as conventional foods include:

• <u>Stevia Select Label</u>: "Suggested Use: Substitute ½ teaspoon of Stevia Select for 4 teaspoons of sugar in food and beverages four times daily. (Stevia Select is 8 times sweeter than sugar.)"



• Young Living Essential Oils web site, <a href="www.youngliving.com">www.youngliving.com</a>: "STEVIA... (Stevia rebaudiana) a dietary supplement that has been used as a sweetener in South America for over 1,500 years. It is 30 times sweeter than sugar and contains virtually no calories....". "STEVIA SELECT... Has long been lauded by the health food community as one of the only alternatives to processed, bleached, refined white sugar. In this revolutionary product, powdered stevia is combined with fructooligosaccharides to add sweetness to any dish without harmful side effects...".

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of H. Tom Warwick, Compliance Officer, at the above letterhead address.

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Sincerely,

Tyler (H) Thornburg
Acting Director, Denver District

